IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

BUTAMAX™ ADVANCED BIOFUELS LLC	)	
Plaintiff,	)	
v.	)	Civ. Nos. 12-1036-SLR 12-1200-SLR
GEVO, INC.,	)	12-1300-SLR
Defendant.	)	

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MEMORANDUM OPINION

Dated: August 3, 2015
Wilmington, Delaware

ROBINSON, District Judge

I. INTRODUCTION

Plaintiff Butamax™ Advanced Biofuels LLC ("Butamax") filed three complaints against defendant Gevo, Inc. ("Gevo"), alleging infringement of U.S. Patent No. 8,241,878 ("the '878 patent") (D.I. 1), on August 14, 2012;[1] alleging infringement of U.S. Patent No. 8,273,558 ("the '558 patent") (Civ. No. 12-1200, D.I. 1), on September 25, 2012; and alleging infringement of U.S. Patent No. 8,283,144 ("the '144 patent") (collectively with the '558 patent, "the Donaldson patents," and with both the '558 and '878, "the patents-in-suit") (Civ. No. 12-1300, D.I. 1), on October 8, 2012. Gevo answered the complaint regarding the '878 patent on December 18, 2012 and counterclaimed for non-infringement and invalidity. (D.I. 30) Gevo answered the complaints regarding the Donaldson patents on November 5, 2012, counterclaiming for invalidity. (Civ. No. 12-1200, D.I. 8; Civ. No. 12-1300, D.I. 7) Butamax answered the counterclaims as to the '878 patent on January 30, 2013 (D.I. 36) and as to the Donaldson patents on November 30, 2012 (Civ. No. 12-1200, D.I. 12; Civ. No. 12-1300, D.I. 11). The cases were coordinated for the purposes of discovery and claim construction. (D.I. 37) After a Markman hearing, a claim construction order issued on February 3, 2015. (D.I. 203; D.I. 219) Presently before the court are Butamax's motion for summary judgment of infringement of certain claims of the patents-in-suit (D.I. 240);[2] Gevo's cross motion for summary judgment of non-infringement of claim 3 of the '889 patent and no willful infringement (D.I. 268);[3] and Gevo's motion for summary judgment

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[1] All references will be to Civ. No. 12-1036 unless otherwise specified.
[2] Civ. No. 12-1200, D.I. 222; Civ. No. 12-1300, D.I. 221.
[3] Civ. No. 12-1200, D.I. 250; Civ. No. 12-1300, D.I. 249.

of invalidity (D.I. 245).[4] The court has jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

II. BACKGROUND

A. The Parties

Butamax is a limited liability corporation organized and existing under the laws of the State of Delaware, with its principal place of business in Wilmington, Delaware. (D.I. 1 at ¶ 1) Gevo is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business in Englewood, Colorado. (D.I. 30 at 4 ¶ 1) Both parties are engaged in research and development of commercial methods to produce isobutanol using biological methods.

B. The Patents-in-Suit

"Engineering of yeast for fermentative production of commercial products is an active and growing field." ('878 patent, 1:32-33) The '878 patent is directed to a method of converting 2,3-dihydroxyisovalerate ("DHIV") to α-ketoisovalerate, (α-KIV) – a step in the isobutanol biosynthetic pathway – catalyzed by a particular type of dihydroxy-acid dehydratase ("DHAD") enzyme not normally found in yeast. DHAD enzymes require a cofactor known as an iron-sulfur cluster ("Fe-S"). In native yeast, Fe-S clusters are assembled and loaded into enzymes in a highly regulated manner. As a result, heterologous DHAD enzymes recombinantly expressed in the cytosol of yeast are not always fully loaded with Fe-S clusters and, therefore, are not fully active. (D.I. 83 at 4) The '878 patent provides "recombinant yeast host cells comprising at least one heterologous Fe-S cluster protein wherein the yeast host has reduced expression

[4] Civ. No. 12-1200, D.I. 224; Civ. No. 12-1300, D.I. 224.

of at least one endogenous Fe-S cluster protein." ('878 patent, 2:17-20) The Donaldson patents are directed to recombinant yeast comprising DNA for recombinant expression of three enzymes – DHAD, a decarboxylase ("DC"), and alcohol dehydrogenase ("ADH") – in the cytosol, and methods of producing isobutanol with such yeast. (D.I. 83 at 5)

III. STANDARD OF REVIEW

"The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). The moving party bears the burden of demonstrating the absence of a genuine issue of material fact. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 415 U.S. 475, 586 n. 10 (1986). A party asserting that a fact cannot be—or, alternatively, is—genuinely disputed must be supported either by citing to "particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations (including those made for the purposes of the motions only), admissions, interrogatory answers, or other materials," or by "showing that the materials cited do not establish the absence or presence of a genuine dispute, or that an adverse party cannot produce admissible evidence to support the fact." Fed. R. Civ. P. 56(c)(1)(A) & (B). If the moving party has carried its burden, the nonmovant must then "come forward with specific facts showing that there is a genuine issue for trial." *Matsushita*, 415 U.S. at 587 (internal quotation marks omitted). The Court will "draw all reasonable inferences in favor of the nonmoving party, and it may not make credibility determinations or weigh the evidence." *Reeves v. Sanderson Plumbing Prods., Inc.,* 530 U.S. 133, 150 (2000).

To defeat a motion for summary judgment, the non-moving party must "do more than simply show that there is some metaphysical doubt as to the material facts." *Matsushita*, 475 U.S. at 586-87; *see also Podohnik v. U.S. Postal Service*, 409 F.3d 584, 594 (3d Cir. 2005) (stating party opposing summary judgment "must present more than just bare assertions, conclusory allegations or suspicions to show the existence of a genuine issue") (internal quotation marks omitted). Although the "mere existence of some alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment," a factual dispute is genuine where "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986). "If the evidence is merely colorable, or is not significantly probative, summary judgment may be granted." *Id.* at 249-50 (internal citations omitted); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986) (stating entry of summary judgment is mandated "against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial").

IV. DISCUSSION

A. The '878 Patent

1. Indefiniteness

The definiteness requirement is rooted in § 112, ¶ 2, which provides that "the specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." "A determination of claim indefiniteness is a legal conclusion that is drawn from the court's performance of its duty as the construer of patent claims." *Personalized Media Comm.,*

LLC v. Int'l Trade Com'n, 161 F.3d 696, 705 (Fed. Cir. 1998). Reiterating the public notice function of patents, the Supreme Court recently explained that "a patent must be precise enough to afford clear notice of what is claimed, thereby 'appris[ing] the public of what is still open to them.'" *Nautilus, Inc. v. Biosig Instruments, Inc.*, ___ U.S. ___, 134 S.Ct. 2120, 2129 (2014) (citations omitted). In balancing the need for clarity with the inherent limitations of the English language, 35 U.S.C. § 112, ¶ 2 requires "that a patent's claims, viewed in light of the specification and prosecution history, inform those skilled in the art about the scope of the invention with reasonable certainty." *Id.*

Most recently in *Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc.*, ___ F.3d ___, 2015 WL 3772402 (Fed. Cir. 2015), the Federal Circuit applied the legal standards set forth in *Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc.*, ___ U.S. ___, 135 S.Ct. 831 (2015), and *Nautilus* to resolve the question of indefiniteness regarding a claim limitation of U.S. Patent No. 5,800,808 ("the '808 patent") – "molecular weight of about 5 to 9 kilodaltons." *Id.* at *1. The *Teva* parties agreed that "molecular weight" could refer to peak average molecular weight (M_p), number average molecular weight (M_n), and weight average molecular weight (M_w), and that "each of these measures is calculated in a different way and would typically yield a different result for a given polymer sample." *Teva Pharmaceuticals*, 2015 WL 3772402 at *4. The '808 specification did not expressly define "molecular weight" and did not use the terms M_p, M_n, or M_w. The parties' experts agreed that the limitation "molecular weight" could refer to any of the three weight measures. *Id.* The district court credited Teva's expert, "Dr. Grant's testimony that M_p is the only type of average molecular weight that can be directly obtained from a chromatogram and calibration curve obtained by the analytical method

described in Example 1 (Size Exclusion Chromatography or SEC)," implying "the use of M_p."[5] *Id.* at *1. The Federal Circuit found no clear error in the district court's reliance on the expert testimony, however, it stated that "accepting these fact findings does not, as Teva suggests, mean that there now exists a **presumption** regarding the meaning of the claim term in the art in general or in the context of this patent." *Id.* at *4. Instead,

> [t]he meaning one of skill in the art would attribute to the term molecular weight in light of its use in the claims, the disclosure in the specification, and the discussion of this term in the prosecution history is a question of law. The district court should not defer to Dr. Grant's ultimate conclusion about claim meaning in the context of this patent nor do we defer to the district court on this legal question.

Id. at *5.

Turning to the prosecution history, the Federal Circuit explained that the parties did not point to any portion of the '808 patent's prosecution history. The prosecution histories of two related patents were considered, U.S. Patent Nos. 6,620,847 ("the '847 patent") and 6,939,539 ("the '539 patent"). For each of these patents, the examiner rejected the claims as indefinite, as the patentee did not specify which measure of molecular weight should be used. *Id.* For the '847 patent, the patentee responded that "'[o]ne of ordinary skill in the art could understand that kilodalton units implies a weight average molecular weight,' i.e., M_w."[6] *Id.* at *6. For the '539 patent, the patentee responded "that a person 'of ordinary skill in the art, upon reviewing the specification,

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[5] Mylan's expert, Dr. Ryu, opined that "although SEC can provide M_p, this disclosure is insufficient . . . in view of the fact that it can also provide M_w and M_n." *Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc.*, 810 F. Supp. 2d 578 (S.D.N.Y. 2011).

[6] The Federal Circuit explained that while such statement is scientifically inaccurate because all three measures could be expressed in kilodaltons does not change the conclusion that "a person of ordinary skill in the art would have understood that the applicants defined the term 'molecular weight' as M_w to gain allowance of the claims." *Teva Pharmaceuticals*, 2015 WL 3772402 at *6.

would understand that 'average molecular weight' refers to the molecular weight at the peak of the molecular distribution curve in Figure 1,' i.e., M_p." *Id.* at *7. The Federal Circuit summarized the evidence and concluded

> that claim 1 is invalid for indefiniteness by clear and convincing evidence because read in light of the specification and the prosecution history, the patentee has failed to inform with reasonable certainty those skilled in the art about the scope of the invention. On this record, there is not reasonable certainty that molecular weight should be measured using M_p.

Id.

In the case at bar, claim 1 of the '878 patent recites:

> 1. A method of converting 2,3-dihydroxyisovalerate to α-ketoisovalerate, comprising providing a recombinant yeast host cell expressing a heterologous dihydroxy-acid dehydratase (DHAD) protein that comprises
> (i) **an amino acid sequence having at least 95% identity to SEQ ID NO: 179 or 187**; and
> (ii) three conserved cysteine residues that correspond to positions 56, 129, and 201 of SEQ ID NO: 179;
> wherein the substrate 2,3-dihydroxyisovalerate is present in the yeast host cell and wherein the expressed heterologous DHAD protein catalyzes the conversion of 2,3-dihydroxyisovalerate to α-ketoisovalerate.

('878 patent, 101:15-27) (emphasis added) The court construed the limitation "having at least 95% identity to" as "at least 95% of amino acid units in the sequence match in an alignment with a reference sequence," but left open the question of indefiniteness for a substantive motion practice after discovery. (D.I. 203)

The claim language does not specify a method of calculating "% identity." The specification explains:

> The term "percent identity", as known in the art, is a relationship between two or more polypeptide sequences or two or more polynucleotide sequences, as determined by comparing the sequences. In the art, "identity" also means the degree of sequence relatedness between polypeptide or polynucleotide sequences, as the case may be, as determined by the match between strings of such sequences. "Identity" and "similarity" can be readily calculated by known methods, including but

> not limited to those described in: 1.) *Computational Molecular Biology* (Lesk, A. M., Ed.) Oxford University: NY (1988); 2.) *Biocomputing: Informatics and Genome Projects* (Smith, D. W., Ed.)Academic: NY (1993); 3.) *Computer Analysis of Sequence Data Part I* (Griffin, A. M., and Griffin, H. G., Eds.) Humania: NJ (1994); 4.) *Sequence Analysis in Molecular Biology* (von Heinje, G., Ed.) Academic (1987); and 5.) *Sequence Analysis Primer* (Gribskov, M. and Devereux, J., Eds.) Stockton: NY (1991).

('878 patent, 11:12-28) The specification goes on to explain that [p]referred methods to determine identity are designed to give the best match between the sequences tested. Methods to determine identity and similarity are codified in publicly available computer programs. Sequence alignments and percent identity calculations **may** be performed using the MegAlign™ program . . . ." (*Id.* at 11:30-35) (emphasis added) The specification describes using the "Clustal method of alignment" which encompasses several varieties of the algorithm including the "Clustal V method of alignment" and "Clustal W method of alignment," and that "[a]fter alignment of the sequences using the Clustal V program, it is possible to obtain a 'percent identity' by viewing the 'sequence distances' table in the same program." (*Id.* at 11:36-67) The specification also defines "sequence analysis software" as "refer[ing] to **any** computer algorithm or software program that is useful for the analysis of nucleotide or amino acid sequences." Such "'[s]equence analysis software' **may** be commercially available or independently developed."[7] (*Id.* at 12:19-23) (emphasis added)

Turning to the prosecution history,[8] certain claims originally contained a limitation "having an amino acid sequence that is at least about 90% identical to the amino acid

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[7] Five examples of commercially available software are provided.

[8] The court constrains itself to the portions of the prosecution history relied on by the parties (approximately 50 pages) as it has neither the time nor the resources to review the 1500 pages of prosecution history provided by the parties for the '878 patent.

sequence as set forth in SEQ ID NO: 114 using the Clustal W method of alignment using the default parameters of GAP PENALTY-10, GAP LENGTH PENALTY-0.1, and Gonnet 250 series of protein weight matrix over the full length of the protein sequence."[9] (D.I. 87 at BJA359-60, claims 12 and 17) The patentee then amended claim 12 deleting the reference to Clustal W, in response to the examiner's objection that "this information is pertinent to the specification, however, not per se a claim limitation." (D.I. 249, ex. 22 at 9, 12) The patentee noted that "[a]lgorithms and methods to determine percent identity are widely-available and well-known to those of skill in the art." (*Id.* at 14)[10] It appears that this claim set was cancelled and the examiner offered amendments to a later claim set, which included a proposed change to the limitation, "having at least 90% **sequence** identity to SEQ ID NO: 179 or SEQ ID NO: 187 . . . ." (D.I. 87 at BJA454, claim 28)[11] In response, the patentee filed an amendment containing a new claim set, which was allowed and contained the disputed limitation, "having at least 90% identity to SEQ ID NO: 179 or SEQ ID NO: 187 . . . ." (D.I. 88 at BJA500, claim 43; BJA1721)

Gevo's expert, Dr. Eddy, opines that "[t]here is no standardized way to align amino acid sequences in the art. On the contrary, there are a variety of methods for aligning amino acid sequences known in the art. The different methods frequently give different results . . . ." (D.I. 248, ex. 4 at ¶¶ 44-45) "[T]here are a variety of equations known in the art for calculating a numerical '% identity' from aligned amino acid sequences, and those various methods yield different results." (*Id.* at ¶ 49) Dr. Eddy

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[9] Cited by Gevo. (D.I. 246 at 8)
[10] Cited by Gevo and Butamax without reference to the joint appendix. (D.I. 246 at 10; D.I. 300 at 2)
[11] Cited by Butamax. (D.I. 269 at 8 n.8) The examiner proposed adding the term "sequence."

explained that "[t]he absence of a single art-recognized way to align amino acid sequences and calculate a numerical '% identity' has long been known in the art, well before the filing date of the '878 patent, and has been discussed in scholarly publications." (*Id.* at ¶ 50) Dr. Eddy then concluded that the disputed limitation is indefinite because the specification "does not identity a particular sequence alignment program that must be used before calculating '% identity,'" instead providing for the calculation of % identity by known methods, with a non-inclusive list of examples. The specification also does not indicate "within a single program all the parameters that must be used to make the sequence alignment." (*Id.* at ¶¶ 76-98) Dr. Eddy avers that different sequence alignment programs can provide different alignments for two given sequences, affecting the calculation of % identity. Moreover, "[d]ifferent methods for calculating '% identity' give different values for a given sequence alignment." (*Id.* at ¶¶ 110-23) For example, when aligning a wild type *S. macacae* sequence to both SEQ ID NO: 179 and 187, the KALIGN sequence alignment program inserts a five amino acid gap in SEQ ID NO: 179 and S. macacae, while the Clustal W2 alignment method inserts a four amino acid external gap at the N-terminus.[12] (*Id.* at ¶¶ 110-113) If internal gaps are counted as part of the denominator when calculating percent identity (as with %Method-1[13]), then the two programs will yield different percent identities. (*Id.* at ¶ 114)

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[12] Even if the court adopts Butamax's expert, Dr. Bonneau's, method of performing two separate pairwise alignments rather than one three-way alignment (D.I. 267 at ¶ 101), the alignment between SEQ ID NO: 187 and wild type *S. macacae* results in an additional internal gap using the KALIGN program as compared to the Clustal W program.

[13] Dr. Bonneau opined that %Method-1 corresponds to the method defined in the MegAlign on-line help and "is the one that the skilled artisan would use in the context of the '878 patent invention." (D.I. 267 at ¶ 69)

Likewise, if external gaps are counted as part of the denominator (as with %Method-6), the two programs will yield different percent identities. (*Id.*)

Butamax's expert, Dr. Bonneau, states that "the specification provides detailed guidance in how to [determine % identity] in the context of the invention," by "direct[ing] the skilled artisan to use a computer program for the analysis, and specifically the MegAlign™ program, together with either Clustal V or Clustal W." Dr. Bonneau explains that "[w]ith the alignment performed, the skilled artisan would utilize the formula specified by the MegAlign™ on-line help to calculate the resulting '% identity' . . . . The person of skill in the art also could use a different program, such as BLAST, that calculates '% identity' using the same formula." (D.I. 267 at ¶¶ 37-39; *see also*, D.I. 265 at ¶¶ 90-94) Dr. Bonneau takes issue with many of Dr. Eddy's calculations and focuses on why a person of ordinary skill would not use certain "% identity" calculation methods. (D.I. 267 at ¶¶ 68, 69, 88)

In summary, the specification identifies a non-inclusive list of five methods to calculate "% identity" and provides that sequence alignment can be performed using any commercially available or independently developed software. The prosecution history does not clarify which alignment program or method of measurement should be used, instead referring to plural methods, which are widely available and well-known. The progression of claims including iterations of the disputed limitations do not inform the present analysis. As the claim limitation at issue uses the calculated "% identity" to determine whether or not the alleged infringing amino acid sequence has "at least 95% identity" to specific amino acid sequences, "the method of measurement is in fact

outcome-determinative in the infringement analysis."[14] *See Takeda Pharm. Co. v. Zydus Pharm. USA, Inc.*, 743 F.3d 1359, 1367 (Fed. Cir. 2014), cert. denied, 135 S. Ct. 711 (2014) (citing *Honeywell International, Inc. v. International Trade Commission*, 341 F.3d 1332 (Fed. Cir. 2003)). Based on the broad and ambiguous language of the specification, the court does not find commonsensible Dr. Bonneau's conclusory assertion that a person of ordinary skill would be directed by the specification to use the MegAlign program (and its online help manual not referred to in the specification).[15] Recognizing that "[a] party cannot transform into a factual matter the internal coherence and context assessment of the patent simply by having an expert offer an opinion on it," the court assesses the indefiniteness of the claim language as a question of law. *Teva Pharmaceuticals*, 2015 WL 3772402 at *5. Consistent with Dr. Eddy's explanation, the court finds that as described by the specification, multiple legitimate methods exist for the performance of sequence alignment and calculation of "% identity," and such methods of measurement can yield different results. A person of ordinary skill in the art, informed by the specification and the prosecution history, would not be apprised with reasonable certainty about the scope of the invention. Claim 1 is indefinite.

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[14] Contrary to Butamax's contention, the "outcome-determinative" evaluation is not predicated solely on the results for Gevo's alleged infringing strain, but must be evaluated generally in the context of notice to the public. *See Takeda Pharm. Co. v. Zydus Pharm. USA, Inc.*, 743 F.3d 1359, 1367 (Fed. Cir. 2014), cert. denied, 135 S. Ct. 711 (2014) (citing *Honeywell International, Inc. v. International Trade Commission*, 341 F.3d 1332 (Fed. Cir. 2003)). Dr. Bonneau's calculations using Gevo's DHAD sequence at issue in this case, which met "the 95% identity threshold under every calculation method and using every program," do not end the inquiry. (D.I. 267 at ¶¶ 46, 105)

[15] Even if the court were to credit this opinion, it would not "mean that there now exists a **presumption** regarding the meaning of the claim term in the art in general or in the context of this patent." *Teva Pharmaceuticals*, 2015 WL 3772402 at *4.

Dependent claim 3 recites "[t]he method of claim 1, wherein the amino acid sequence of the heterologous DHAD protein comprises SEQ ID NO: 187." ('878 patent, 101:30-33) Dr. Bonneau avers that because "claim 3 specifies a particular sequence, the '% identity' limitation of claim 1 does not come into play in determining infringement." (D.I. 267 at ¶ 176) The court disagrees as dependent claim 3 is susceptible to two different interpretations. Under one reading, the limitation becomes "SEQ ID NO: 187;" and under the second, "an amino acid sequence having at least 95% identity to SEQ ID NO: 187." Under the court's analysis above, the second reading of the limitation would be indefinite. Moreover, that claim 3 is susceptible to two different readings cannot reasonably apprise a person of ordinary skill in the art of its scope. Claim 3 is indefinite.[16]

2. Infringement

As the court finds the "% identity" limitation in claim 1 and dependent claim 3 indefinite, the court cannot complete a meaningful infringement analysis.[17] *See Markman*, 52 F.3d at 976. Additionally, the claims are invalid and, therefore, not infringed. *Exergen Corp. v. Wal–Mart Stores, Inc.*, 575 F.3d 1312, 1320 (Fed. Cir. 2009) ("invalid claim[s] cannot give rise to liability for infringement") (citation omitted); *Wahpeton Canvas Co. v. Frontier, Inc.*, 870 F.2d 1546, 1553 (Fed. Cir. 1989) (if an independent claim is not infringed, any claim depending thereon is not infringed). Accordingly, the court denies Butamax's motion for summary judgment of infringement

[16] As the court finds claims 1 and 3 indefinite, it does not reach Gevo's arguments regarding obviousness and unpatentable subject matter regarding the '878 patent.
[17] The remaining asserted dependent claims do not modify the indefinite limitation of claim 1 and, therefore, are also not amenable to an infringement analysis.

of claim 3 under the doctrine of equivalents and grants Gevo's motion for summary judgment of non-infringement in this regard.

B. The Donaldson Patents

1. Lack of written description and enablement

The statutory basis for the enablement and written description requirements, § 112 ¶1, provides in relevant part:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same . . . .

"The enablement requirement is met where one skilled in the art, having read the specification, could practice the invention without 'undue experimentation.'" *Streck, Inc. v. Research & Diagnostic Systems, Inc.*, 665 F.3d 1269, 1288 (Fed. Cir. 2012) (citation omitted). "While every aspect of a generic claim certainly need not have been carried out by the inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention." *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1366 (Fed. Cir. 1997). The specification need not teach what is well known in the art. *Id.* (citing *Hybritech v. Monoclonal Antibodies, Inc.,* 802 F.2d 1367, 1384 (Fed. Cir. 1986)). A reasonable amount of experimentation may be required, so long as such experimentation is not "undue." *ALZA Corp. v. Andrx Pharmaceuticals, Inc.*, 603 F.3d 935, 940 (Fed. Cir. 2010).

"Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual

considerations." *Martek Biosciences Corp. v. Nutrinova, Inc.*, 579 F.3d 1363, 1378 (Fed. Cir. 2009) (citing *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988)). The Federal Circuit has provided several factors that may be utilized in determining whether a disclosure would require undue experimentation: (1) the quantity of experimentation necessary; (2) the amount of direction or guidance disclosed in the patent; (3) the presence or absence of working examples in the patent; (4) the nature of the invention; (5) the state of the prior art; (6) the relative skill of those in the art; (7) the predictability of the art; and (8) the breadth of the claims. *In re Wands*, 858 F.2d at 737. These factors are sometimes referred to as the "Wands factors." A court need not consider every one of the Wands factors in its analysis, rather, a court is only required to consider those factors relevant to the facts of the case. *See Streck, Inc.*, 655 F.3d at 1288 (citing *Amgen, Inc. v. Chugai Pharm. Co., Ltd.*, 927 F.2d 1200, 1213 (Fed. Cir. 1991)).

The enablement requirement is a question of law based on underlying factual inquiries. *See Green Edge Enterprises, LLC v. Rubber Mulch Etc., LLC*, 620 F.3d 1287, 1298-99 (Fed. Cir. 2010) (citation omitted); *In re Wands*, 858 F.2d at 737. Enablement is determined as of the filing date of the patent application. *In re '318 Patent Infringement Litigation*, 583 F.3d 1317, 1323 (Fed. Cir. 2009) (citation omitted). The burden is on one challenging validity to show, by clear and convincing evidence, that the specification is not enabling. *See Streck, Inc.*, 665 F.3d at 1288 (citation omitted).

A patent must also contain a written description of the invention. 35 U.S.C. § 112, ¶ 1. The written description requirement is separate and distinct from the enablement requirement. *See Ariad Pharmaceuticals, Inc. v. Eli Lilly and Co.*, 598 F.3d

1336, 1351 (Fed. Cir. 2011). It ensures that "the patentee had possession of the claimed invention at the time of the application, i.e., that the patentee invented what is claimed." *LizardTech, Inc. v. Earth Resource Mapping, Inc.*, 424 F.3d 1336, 1344-45 (Fed. Cir. 2005). The Federal Circuit has stated that the relevant inquiry – "possession as shown in the disclosure" – is an "objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art. Based on that inquiry, the specification must describe an invention understandable to that skilled artisan and show that the inventor actually invented the invention claimed." *Ariad*, 598 F.3d at 1351.

This inquiry is a question of fact; "the level of detail required to satisfy the written description requirement varies depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology." *Id.* (citation omitted). In this regard, a defendant must provide clear and convincing evidence that persons skilled in the art would not recognize in the disclosure a description of the claimed invention. *See PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1306-17 (Fed. Cir. 2008) (citation omitted). While compliance with the written description requirement is a question of fact, the issue is "amenable to summary judgment in cases where no reasonable fact finder could return a verdict for the non-moving party." *Id.* at 1307 (citing *Invitrogen Corp. v. Clontech Labs., Inc.*, 429 F.3d 1052, 1072-73 (Fed. Cir. 2005)).

The asserted claims of the Donaldson patents are directed to recombinant yeast encoding the engineered isobutanol pathway and providing for recombinant expression

of three enzymes – DHAD, DC, and ADH – in the cytosol, as well as methods of producing isobutanol with such yeast. Representative claim 1 of the '558 patent recites:

> 1. A recombinant yeast host cell comprising genes encoding an engineered isobutanol biosynthetic pathway, wherein said isobutanol biosynthetic pathway increases the production of isobutanol as compared to naturally occurring amounts of isobutanol made by unmodified yeast and comprises the following substrate to product conversions:
>
> (a) 2,3-dihydroxy-isovalerate to a-ketoisovalerate;
>
> (b) the a-ketoisovalerate from (a) to isobutyraldehyde; and
>
> (c) the isobutyraldehyde from (b) to isobutanol,
>
> wherein
>
> (i) the substrate to product conversion of step (a) is performed by a recombinantly expressed acetohydroxy acid dehydratase enzyme;
>
> (ii) substrate to product conversion of step (b) is performed by a recombinantly expressed decarboxylase enzyme; and
>
> (iii) the substrate to product conversion of step (c) is performed by a recombinantly expressed alcohol dehydrogenase enzyme,
>
> wherein the recombinantly expressed enzymes of (i) to (iii) are expressed in the cytosol, and wherein said recombinant yeast host cell is capable of producing isobutanol through the substrate to product conversions of (a) to (c).

('558 patent, 69:43-67) Gevo argues that the asserted "claims expressly cover cells where only the last three enzymes are [heterologously] expressed" and that the specification does not adequately describe or enable this embodiment. (D.I. 246 at 26-27) Gevo's expert, Dr. Voigt, opines that

> yeast engineered to express the claimed three-step pathway would not operate to produce isobutanol through these overexpressed pathway steps, because one of skill in the art would not believe any (or at most only an insignificant amount of) DHIV starting material needed for the claimed pathway is present in the cytosol.

(D.I. 249, ex. 12 at ¶ 85) Moreover, Dr. Voight avers that the specification does not explain how the expression of the last three enzymes of the pathway would result in increased isobutanol production. (*Id.* at ¶¶ 85-102) Dr. Voigt further explains that a

great deal of experimentation would be required to create such a recombinant yeast. (*Id.* at ¶¶ 113-148)

Butamax's expert, Dr. Smolke, disagrees and opines that the claims are not limited to pathways with three recombinant enzymes and that the specification provides working examples. (D.I. 265 at ¶¶ 19-51) By way of example, Dr. Smolke explains that the specification is directed to "recombinant yeast host cells expressing one or more heterologous genes" and that a person or ordinary skill, "following the teachings of the patent and prior art, [would be] capable of producing recombinant yeast host cells recombinantly expressing heterologous DHAD, DC, and ADH . . . ." (*Id.* at ¶¶ 27-29)

The art in the case at bar is generally unpredictable. (D.I. 265 at ¶ 44; D.I. 249, ex. 12 at ¶ 132) The disagreement between the experts on whether one of ordinary skill could practice the invention without undue experimentation and whether the inventors had possession of the invention present genuine disputes of material fact better left to the province of the jury.

2. Infringement

Gevo raises two issues of fact as to the infringement of the Donaldson patents – whether Gevo's strains make isobutanol through the contiguous pathway recited by the claims, i.e., DHAD reaction to DC reaction to ADH reaction and, to the extent there is isobutanol made through these contiguous reactions, whether such isobutanol is produced in an "increased amount." In support of these arguments, Gevo directs the court to Dr. Voigt's report, wherein he opines that "[t]here is ample evidence that endogenous enzymes may be involved in isobutanol production in Gevo's lead strains, and zero evidence that they are not." (D.I. 249, ex. 48 at ¶ 14) Moreover, Dr. Voigt

explained that there is no evidence that the increased isobutanol is produced through the claimed recombinantly expressed enzyme steps recited above. (*Id.* at ¶¶ 15-19; *see also* ex. 12 at ¶ 32)

In contrast, Dr. Smolke opines that Gevo's lead strains "have DHIV flowing in a continuous flux of substrate to product through three steps to produce isobutanol. There is no evidence . . . to suggest the high yields of isobutanol . . . come entirely through alternative pathways." (D.I. 243 at ¶ 139) Moreover, Dr. Smolke concludes that "[i]f isobutanol is produced through other pathways in addition to the claimed pathway, it is inconsequential." (*Id.* at ¶ 140)

Drawing all reasonable inferences in favor of the non-movant Gevo, the court concludes that the expert opinions are in direct conflict, therefore, there are genuine issues of material fact as to whether Gevo's strains infringe the asserted claims. Butamax's motion for summary judgment of infringement is denied.

C. Willful Infringement

The Federal Circuit has set forth a two-pronged standard for establishing willfulness in *In re Seagate Technology, LLC*, 497 F.3d 1360 (Fed. Cir. 2007), the first prong of which states:

> [T]o establish willful infringement, a patentee must show by clear and convincing evidence that the infringer acted despite an objectively high likelihood that its actions constituted infringement of a valid patent. The state of mind of the accused infringer is not relevant to this objective inquiry.

Id. at 1371 (internal citations omitted). The existence of this objective risk is "determined by the record developed in the infringement proceeding." *Id.* "Objective recklessness will not be found where the accused infringer has raised a 'substantial

question' as to the validity or noninfringement of the patent," even if the jury ultimately reaches a verdict of infringement. *Bard Peripheral Vascular, Inc. v. W.L. Gore & Associates, Inc.*, 776 F.3d 837, 844 (Fed. Cir. 2015) (citations omitted); *see also Spine Solutions, Inc. v. Medtronic Sofamor Danek USA, Inc.*, 620 F.3d 1305, 1319 (Fed. Cir. 2010) (holding that objective prong is generally not met "where an accused infringer relies on a reasonable defense to a charge of infringement"); *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1336 (Fed. Cir. 2009) (concluding that accused infringer presented a substantial question of noninfringement which precluded a finding of objective recklessness despite the jury's ultimate finding of infringement).

If the objective prong is satisfied, the patentee must next establish that "this objectively-defined risk (determined by the record developed in the infringement proceeding) was either known or so obvious that it should have been known to the accused infringer." *Seagate*, 497 F.3d at 1371. This subjective prong hinges on the fact finder's assessments of the credibility of witnesses. *LG Elecs. U.S.A., Inc. v. Whirlpool Corp.*, 798 F.Supp.2d 541, 557–58 (D.Del.2011). "The drawing of inferences, particularly in respect of an intent-implicating question such as willfulness, is peculiarly within the province of the fact finder that observed the witnesses." *Liquid Dynamics Corp. v. Vaughan Co.*, 449 F.3d 1209, 1225 (Fed.Cir.2006).

In the case at bar, Gevo asserted invalidity and non-infringement arguments for the '889 patent and Gevo's motion for summary judgment of the '889 patent is granted as to indefiniteness. With respect to the Donaldson patents, Gevo's invalidity and non-infringement arguments, at minimum, are credible and reasonable theories supported

by expert testimony. Gevo's motion for summary judgment of no willful infringement is granted.[18]

V. CONCLUSION

For the foregoing reasons, the court grants in part Gevo's motion for summary judgment of invalidity (D.I. 245);[19] denies Butamax's motion for summary judgment of infringement of the patents-in-suit (D.I. 240);[20] and grants Gevo's cross motion for summary judgment of non-infringement of claim 3 of the '889 patent and no willful infringement (D.I. 268).[21] An appropriate order shall issue.

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[18] The court recognizes Butamax's arguments against summary judgment of no willfulness based on the concurring opinions in both *Halo Elecs., Inc. v. Pulse Elecs., Inc.*, 769 F.3d 1371, 1383 (Fed.Cir.2014) (O'Malley, J., concurring), and *Bard Peripheral Vascular, Inc. v. W.L. Gore & Associates, Inc.*, 776 F.3d 837, 847 (Fed. Cir. 2015) (Hughes, J., concurring), calling for a review of the willfulness jurisprudence. However, the court declines to depart from the application of the controlling law, *Seagate*'s two-part test, until such time as the Federal Circuit does so.

[19] Civ. No. 12-1200, D.I. 224; Civ. No. 12-1300, D.I. 224.

[20] Civ. No. 12-1200, D.I. 222; Civ. No. 12-1300, D.I. 221.

[21] Civ. No. 12-1200, D.I. 250; Civ. No. 12-1300, D.I. 249.